District Judge Marsha J. Pechman

UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF WASHINGTON

Arrow Reliance, Inc., dba Darwin's Natural Pet Products, Plaintiff, v. Robert M. Califf,[1] *et al.*, Defendants.	No. 2:22-cv-01057 **DEFENDANTS' OPPOSITION TO PLAINTIFF'S MOTION FOR A TEMPORARY RESTRAINING ORDER AND PRELIMINARY INJUNCTION** **NOTING DATE: August 2, 2022**

INTRODUCTION

Plaintiff Arrow Reliance, Inc., dba Darwin's Natural Pet Products (Darwin's) asks this Court to enjoin the U.S. Food and Drug Administration (FDA) from notifying the public that some of Darwin's products may contain dangerous *Salmonella*. The Court should decline that request because Darwin's has failed to satisfy the requirements for such extraordinary relief.

First, Darwin's is unlikely to succeed on the merits. The Court lacks jurisdiction because Darwin's claims are not ripe, and (even if they were) FDA has not taken "agency action"—let alone "final" agency action—that may be challenged under the Administrative Procedure Act (APA). Another federal district recently reached precisely this conclusion in refusing to preliminarily enjoin FDA from issuing a similar public statement. *See Wedgewood Village*

[1] Defendants substitute Robert M. Califf for Janet Woodcock pursuant to Federal Rule of Civil Procedure 25(d).

Pharmacy, LLC v. FDA, 2022 WL 1591787 (D. N.J. May 19, 2022). Darwin's also challenges an FDA guidance document, but FDA need not rely on this or any guidance document to issue a public statement, and in any event, another court recently found that the guidance document in question was not final agency action either. *Lystn, LLC v. FDA*, 2020 WL 5513409 (D. Colo. Sept. 14, 2020), *aff'd* 2021 WL 4006184 (10th Cir. Sept. 3, 2021).

Even if the Court had jurisdiction, Darwin's claims are baseless. FDA is not required to find that Darwin's products pose an "imminent danger" to public health or are "adulterated" before issuing a public statement. Moreover, FDA's guidance document is not a "legislative rule" and has no bearing on FDA's authority to issue a public statement. And Darwin's cannot prevail under 42 U.S.C. § 1983 on its First Amendment "compelled speech" claim because (1) § 1983 does not furnish a cause of action against the federal government, (2) FDA has not "compelled" speech, and (3) even if FDA's recommendation were compulsion, Darwin's provides no evidence for its assertion that FDA recommended that Darwin's describe its products as "adulterated."

Second, Darwin's fails to establish that it is likely to suffer irreparable harm absent an injunction—a separate basis for the Court to deny injunctive relief. Instead, without knowing what an FDA statement will say, it speculates that such a statement will generate harmful publicity. Such speculation cannot establish a likelihood of irreparable harm. But even if it could, Darwin's itself has already publicized the matter by filing this lawsuit in open court.

Finally, the balance of equities and public interest favor allowing FDA to continue to apply its expertise when discharging its public health duties, including informing the public about its investigations and warning the public as it finds appropriate. The Court should reject Darwin's extraordinary attempt to prevent FDA from sharing scientific evidence about contaminated products with the public. The equities and public interest favor consumers having more information about potential health risks to pets and caretakers, not less.

BACKGROUND

To enable FDA to carry out its mission to "protect the public health by ensuring that . . . foods are safe, wholesome, sanitary, and properly labeled," 21 U.S.C. § 393(b)(2), the Federal Food, Drug, and Cosmetic Act (FDCA) gives the agency authority to "conduct examinations and investigations," *id.* §§ 372(a)(1); 374. Sometimes those investigations result in an enforcement proceeding brought by the Department of Justice if, for example, they reveal that "adulterated" food is shipped in interstate commerce. *See, e.g., id.* §§ 331(a), 332 (authorizing injunction proceedings). But separate and apart from this authority, FDA has inherent authority, confirmed by another provision of the FDCA, to communicate information to the public, including information resulting from its investigations. *Id.* § 375(b); *see also Hoxsey v. Folsom*, 155 F. Supp. 376, 378 (D.D.C. 1957).

Importantly, the agency's authority to issue public statements does not depend on the agency finding that food is "adulterated" or that a manufacturer has violated the law. And while the first sentence of § 375(b) expressly recognizes that FDA may alert the public to "imminent danger to public health or gross deception of consumers," *id.*, nothing prohibits FDA from making the public aware of the results of its investigations when no such imminent danger or gross deception is found. To the contrary, the second sentence states that "[n]othing in this section"—including, of course, the first sentence—"shall be construed to prohibit the Secretary from collecting, reporting, and illustrating the results of the investigations of the Department." *Id.*

In this case, FDA conducted an investigation and found that samples of Darwin's product contained *Salmonella*. The agency recommended, but did not require, that Darwin's institute a voluntary recall and alert the public. It stated that if Darwin's chose not to recall its products and alert the public, FDA would issue its own public statement. Darwin's responded by bringing this suit, seeking temporary and preliminary relief to prohibit FDA from making a public statement.

LEGAL STANDARD

Injunctive relief is "an extraordinary remedy that may only be awarded upon a clear showing that the plaintiff is entitled to such relief." *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 22 (2008). Obtaining either a temporary restraining order or preliminary injunction "requires" the movant to "demonstrate (1) that he is likely to succeed on the merits, (2) that he is likely to suffer irreparable harm in the absence of preliminary relief, (3) that the balance of equities tip in his favor, and (4) that an injunction is in the public interest." *Stormans, Inc. v. Selecky*, 586 F.3d 1109, 1127 (9th Cir. 2009); *New Motor Vehicle Bd. of Cal. v. Orrin W. Fox Co.*, 434 U.S. 1345, 1347 n.2 (1977) (standards for TRO and PI are the same). "When the government is a party, the third and fourth" factors merge. *East Bay Sanctuary Covenant v. Garland*, 994 F.3d 962, 984 (9th Cir. 2020).

The first factor "is a threshold inquiry." *Garcia v. Google, Inc.*, 786 F.3d 733, 740 (9th Cir. 2015). "[W]hen a plaintiff has failed to show the likelihood of success on the merits," the Court "need not consider the remaining three" requirements. *Id.*

ARGUMENT

I. Darwin's Fails To Show A Likelihood Of Success On The Merits

A. The Court lacks jurisdiction

Darwin's challenges the legality of an unissued agency press release or public statement whose contents are unknown. As another federal district court recently concluded, the requirements of ripeness and "final agency action" preclude such a challenge. *See Wedgewood*, 2022 WL 1591787, at *4–5. For those reasons, this Court lacks jurisdiction and Darwin's cannot succeed on its claims. *Wolfson v. Brammer*, 616 F.3d 1045, 1053 (9th Cir. 2010) (ripeness is jurisdictional); *Oregon Natural Desert Ass'n v. U.S. Forest Service*, 465 F.3d 977, 982 (9th Cir. 2006) (final agency action is jurisdictional).

In *Wedgewood*, a drug compounding pharmacy asked a district court to preliminarily enjoin FDA from issuing a public statement about the insanitary conditions FDA observed at

Wedgewood's facility after the company declined to voluntarily institute a recall. The court refused, finding that Wedgewood's claims were unripe and did not challenge "final agency action" reviewable under the APA. The court emphasized that "the content and potential ramifications" of the unissued public statement "remain purely hypothetical and speculative," and therefore it could not meaningfully review Wedgewood's claims. *Id.* at *4. Citing the APA's definition of "agency action," the court also explained that the "yet to be issued notice or press release is not agency action," and could not be "final" because "the statements have not been issued." *Id.* This Court should follow *Wedgewood* and conclude that Darwin's cannot challenge an agency press release or public statement, let alone an unissued one.

1. The dispute is not ripe

The dispute between the parties "is not ripe for adjudication" because "it rests upon contingent future events that may not occur as anticipated." *Texas v. United States*, 523 U.S. 296, 300 (1998). Specifically, unless and until FDA issues a public statement, the content of any statement is unknown and Darwin's claims cannot be considered without impermissibly speculating about what the statement will say. For example, Darwin's invites this Court to adjudicate whether FDA may describe Darwin's products as "adulterated." *See* ECF No. 7 (Am. Compl.) ¶ 27; ECF No. 3 (Pl. Mot.) at 6–17. But because FDA has not issued a statement, it is still undetermined whether that statement *will* describe Darwin's products as "adulterated." The ripeness doctrine therefore requires that the Court decline to intervene at this stage. *See Ohio Forestry Ass'n v. Sierra Club*, 523 U.S. 726, 733 (1998) (holding that a case is not ripe when "the courts would benefit from further factual development of the issues presented").

2. Darwin's does not challenge final agency action

Even if a dispute were ripe, Darwin's could not bring suit under the APA because it does not challenge any agency action within the meaning of the statute, let alone agency action that is "final." As relevant here, the APA authorizes judicial review of "final agency action for which there is no other adequate remedy in a court." 5 U.S.C. § 704. To the best of Defendants'

knowledge, "[n]o court has ever found a press release to be a final agency action under the APA" in the circumstances at issue in this case. *Trudeau v. FTC*, 384 F. Supp. 2d 281, 289 (D.D.C. 2005), *aff'd on other grounds*, 456 F.3d 178 (D.C. Cir. 2006); *accord Trudeau*, 456 F.3d at 189 ("As the district court noted, we have never found a press release of the kind at issue here to constitute 'final agency action' under the APA."). This Court should not be the first.

(a) ***No "agency action."*** Indeed, the public statement that Darwin's seeks to enjoin is "no[t] agency action—let alone 'final agency action'—within the meaning of the APA," *Wedgewood*, 2022 WL 1591787, at *4, because—even if such a statement were issued—it would not meet the statutory definition of that term. The APA defines "agency action" to mean a "rule, order, license, sanction, relief, or equivalent or denial thereof, or failure to act." *See* 5 U.S.C. § 511(13). Applying that definition, courts have held that agency press releases and public statements—including those issued under § 375(b)—are not "agency action" subject to review under the APA. *See Pharmaceutical Mfrs. Ass'n v. Kennedy*, 471 F. Supp. 1224, 1227–31 (D. Md. 1979) (holding that FDA's dissemination of information under 21 U.S.C. § 375(b) is not "agency action"); *Hearst Radio, Inc. v. FCC*, 167 F.2d 225, 227 (D.C. Cir. 1948) (holding that an agency's publication of information harmful to a company's reputation is not a "sanction" or other "agency action" under the APA).

(b) ***No "final" agency action.*** Even if the public statement FDA might issue were an "agency action," it would not be "final." An "agency action" is "final" only when it (1) "mark[s] the consummation of the agency's decision-making process" and (2) is an action "by which rights or obligations have been determined, or from which legal consequences will flow." *Bennett v. Spear*, 520 U.S. 154, 177–78 (1997). Courts have repeatedly held that agency communications—including FDA warning letters—that merely state the agency's position on a matter within its purview and have no legal effect are not final agency actions. *See, e.g.*, *Dietary Supplemental Coalition, Inc. v. Sullivan*, 978 F.2d 560, 563 (9th Cir. 1992); *Holistic Candlers & Consumer Ass'n v. FDA*, 664 F.3d 940, 944–45 (D.C. Cir. 2012); *Swisher Int'l, Inc. v. FDA*, 2022

WL 320889, at *5 (11th Cir. Feb. 3, 2022); *Hi-Tech Pharm., Inc. v. Hahn*, 2020 WL 3498588, at *5 (D.D.C. June 29, 2020); *United States v. Allgyer*, 2012 WL 355261, at *4 n.16 (E.D. Pa. Feb. 3, 2012); *Schering-Plough Healthcare Products, Inc. v. Schwarz Pharma, Inc.*, 547 F. Supp. 2d 939, 945 (E.D. Wis. 2008). Notably, FDA's warning letters are, like agency press releases or public statements, accessible to the public.[2]

Holistic Candlers is instructive. There, FDA issued public warning letters to ear candle manufacturers and distributors advising them that FDA considered their products to be adulterated and misbranded. *Holistic Candlers*, 664 F.3d at 942. Some of the letter recipients sought judicial review of the warning letters. *Id.* The D.C. Circuit concluded that the warning letters were not final agency action. *Id.* at 943. First, the warning letters did not mark the "consummation" of FDA's decision-making process because they did not commit the agency to enforcement action. *Id.* at 944. Second, the warning letters did not "represent a decision determining rights or obligations, or one from which legal consequences flow," because they simply "communicate[d] the agency's position on a matter" and did not "compel[] action" by either the recipients or the agency. *Id.*

For similar reasons, any press release or public statement warning the public about Darwin's products would not be final agency action. There cannot be a consummation of FDA's decisionmaking process where, as here, the statement that supposedly "consummates" it has not even been issued. Moreover, the statement would not determine rights or obligations or create legal consequences. Rather, it would simply inform the public about FDA's findings regarding Darwin's products. It would not compel action by either Darwin's or the agency. As one court has explained, a statement authorized under § 375(b)—"mak[es] no order[,] . . . adjudicate[s] no rights[,] . . . [and] issu[es] no direction[]." *Hoxsey*, 155 F. Supp. at 378. It simply "disseminat[es] information and warn[s] the public." *Id.*; *see also Dimare Fresh, Inc. v. United States*, 808 F.3d

[2] *See* https://go.usa.gov/xu7zH.

1301, 1311 (Fed. Cir. 2015) ("FDA's public warnings did not restrict the Tomato Producers from selling their produce, nor did it place any restriction on how they may use or dispose their tomatoes.").

Even if this Court were to find that an unissued press release or statement were final agency action, Darwin's claim fails because it relies on speculation that such a statement would depend on an FDA guidance document on which Darwin's asserts FDA based a conclusion that Darwin's products are "adulterated." Pl. Mot. 11–15. That speculation is yet another reason why Darwin's claims are unripe. FDA does not need to rely on a guidance document or make a determination that a product is adulterated before issuing a public statement. Rather, FDA would determine whether a product is adulterated in the course of initiating an enforcement action, which is not at issue here.

In addition, as another court recently confirmed, that guidance document, a Compliance Policy Guide (CPG) called "*Salmonella* in Food for Animals,"[3] is not final agency action either. *Lystn,* 2020 WL 5513409, at *2. Rather, it "simply provides information to staff members concerning how to interpret 21 U.S.C. § 342 for the purpose of determining whether further administrative proceedings are necessary." *Id.* at 4. The court determined that the CPG "d[id] not create any legal right" and that FDA "derive[d] no enforcement authority from the CPG," so it was not final agency action and the court lacked jurisdiction over the plaintiff's challenge. *Id.* If this Court were to reach the issue, it should come to the same conclusion.

Accordingly, even if FDA's unissued press release or statement constitutes an "agency action" (it does not), it is not "final" and therefore is not subject to judicial review under the APA. And since the unissued press release or statement need not rely on the CPG, and that CPG is not final agency action either, the Court also lacks jurisdiction over Darwin's challenge to the CPG as well.

[3] Available at https://go.usa.gov/xSyYz.

B. Darwin's claims are meritless

Even if the Court had jurisdiction, Darwin's two claims for relief fail. First, it asserts an APA claim that FDA impermissibly relied on the CPG "to justify its position that any presence of Salmonella in Darwin's product rendered the product adulterated." Am. Compl. ¶ 27. Darwin's also argues that FDA has no authority to issue a public statement absent "imminent danger," which (according to Darwin's) FDA can only find if (1) Darwin's agrees to a recall or (2) FDA initiates an enforcement action. Pl. Mot. 9–11. Second, Darwin's brings a claim under § 1983 alleging that FDA sought to compel speech in violation of the First Amendment. Am. Compl. ¶¶ 17–24; Pl. Mot. 17–19. Neither claim is likely to succeed.

1. Darwin's APA claim fails.

Darwin's APA claim is based on two separate theories, neither of which is tenable.

Darwin's first theory challenges FDA's authority to issue a press release or public statement on the ground that FDA impermissibly relied on the CPG to determine that Darwin's products are "adulterated." *See* Am. Compl. ¶ 27. As an initial matter, the premise underlying that theory is false: nothing in § 375(b), elsewhere in the FDCA, or in any other statute makes FDA's authority to issue a public statement dependent upon a finding that a product is "adulterated." Although FDA cited the CPG in an email to Darwin's, *see* ECF No. 4 at 11, it has never suggested that a decision to issue a public statement would be based on a conclusion that Darwin's products are "adulterated" or that the public statement itself would claim that those products are "adulterated." FDA's "position" on whether Darwin's products are adulterated, *see* Am. Compl. ¶ 27, is therefore irrelevant to its authority to issue a public statement.

Even if Darwin's were correct that FDA needed to find that a product were "adulterated" before making a public statement, its theory that FDA improperly relied on the CPG would fail because the CPG is not a "legislative rule" requiring notice and comment, and FDA did not impermissibly treat it as binding. Contrary to Darwin's suggestion, Pl. Mot. 12–13, the CPG does not mandate that FDA take any action when its considerations are met. CPG at 6–7. Rather, it

informs the FDA field office's recommendation about whether to take regulatory action, which is only the initial step in a process that requires input from other FDA offices, as well as the Department of Justice (for injunction or seizure actions), before a final decision is made.[4] And, contrary to Darwin's argument, FDA did not treat the CPG as binding or consider noncompliance with the guidance as itself a violation of law. *See* Am. Compl. ¶ 30. Rather, the agency cited the CPG in an email to Darwin's to explain the agency's view of how § 342 applies and assist Darwin's in its compliance efforts. ECF No. 4 at 11. Darwin's may disagree with the CPG, but the proper way to adjudicate that disagreement—or more broadly, any disagreement it has with how FDA applies § 342—is as a defense in any future enforcement action, not through an injunction at this stage. But Darwin's cannot short-circuit the process and preempt the bringing of any enforcement action. *See Ewing v. Mytinger & Casselberry*, 339 U.S. 594, 600–01 (1950).

Darwin's second theory argues that FDA cannot issue a public statement without finding "imminent danger," and FDA cannot find "imminent danger" unless either Darwin's agrees to a recall or FDA initiates an enforcement action. Pl. Mot. 9–11; *see also* Am. Compl. ¶¶ 15, 31. But as explained above, FDA is not limited to issuing statements only when there is "imminent danger to health." Darwin's in effect asks this Court to draw a negative inference that because the first sentence of § 375(b) *authorizes* warning of "imminent danger to health," it *forbids* all other warnings. But the second sentence of § 375(b) refutes this negative inference: "Nothing in this section shall be construed to prohibit the Secretary from collecting, reporting, and illustrating the results of the investigations of the Department." 21 U.S.C. § 375(b). This language was included not to restrict FDA's authority, but to "continue the authority the Department of Agriculture[5] has had for 30 years or more to collect, illustrate, and report the results of investigations." *See*

[4] *See* Investigations Operation Manual §§ 2.2.6.2 (seizure process), 2.2.8 (injunctions), available at https://go.usa.gov/xSmJ3; Regulatory Procedures Manual §§ 6-1-5, 6-1-6 (seizures), 6-2-10 (injunctions) available at https://go.usa.gov/xSmJ4.

[5] When the FDCA was enacted in 1938, FDA was part of the Department of Agriculture.

Katzen Decl. Ex. A, at 32 (S. Rept. No. 361 to accompany S. 5, 74th Cong., 1st Sess. 31 (1935)). Because § 375(b) "place[s] within the express scope of the duties of the Secretary something that was one of his implied functions," "even in the absence of this statute there would be nothing to prevent [FDA] from disseminating information to the public." *Hoxsey*, 155 F. Supp. at 378; *see also Diapulse Mfg. Corp. of Am.*, 262 F. Supp. at 730 (recognizing that § 375(b) does not limit the agency to disseminating information about imminent danger to the public health).

Even if the statutory language and legislative history were ambiguous, FDA has long interpreted the statute not to limit the agency's authority to disseminate information to the public. *See* Policy Statement; Class II Medical Device, 50 Fed. Reg. 43060–01 (Oct. 23, 1985) (explaining that "dissemination of information about or public education with respect to investigations FDA has conducted about the products for which FDA is responsible is an exercise of the agency's implicit authority under section 705(b) of the [FDCA]"). That interpretation is entitled to deference. *See Chevron, U.S.A. v. Nat. Res. Def. Council*, 467 U.S. 837, 842–43 (1984).

Finally, even if § 375(b) required a finding of imminent danger, it does not (contrary to Darwin's suggestion) require FDA to obtain Darwin's agreement to a recall or bring an enforcement action before issuing a public statement or press release. To the contrary, the "imminent danger" determination is committed to the "opinion of the Secretary," and exists entirely apart from the enforcement mechanisms found elsewhere in the FDCA. The Court should reject Darwin's attempt to hamstring the agency's power to alert the public to imminent dangers with prerequisites found nowhere in the text of the statute.

In short, even if FDA's unissued public statement were final agency action, Darwin's has not carried its burden to show a likelihood of success on its APA claim.

2. Darwin's cannot prevail on its First Amendment claim

Darwin's fares no better when it argues that it is likely to succeed on its argument in Count I of the complaint, which alleges a violation of 42 U.S.C. § 1983. ECF No. 1 ¶ 19.

First, Count I fails to state a claim because 42 U.S.C. § 1983 creates a cause of action for actions "under color of" the laws of "any State[,] Territory[,] or the District of Columbia," not the federal government. 42 U.S.C. § 1983. By its own terms, § 1983 "is of only limited scope" and "does not reach . . . actions of the Federal Government." *District of Columbia v. Carter*, 409 U.S. 418, 424–25 (1973).

Second, FDA did not compel Darwin's to speak. Rather, it *recommended* that Darwin's "conduct a voluntary recall and issue a press release to the public." ECF No. 4 at 10. While FDA stated that it would issue its own statement if Darwin's did not follow this recommendation,[6] it has never suggested that Darwin's was required either to conduct the recall or issue its own statement. Darwin's desire to prevent *FDA* from speaking does not somehow convert FDA's recommendation into compulsion.

Finally, Darwin's alleges that FDA required it to state that its pet food was "adulterated," Am. Compl. ¶ 16, but has provided no evidence for that allegation. Indeed, other recent press releases from pet food manufacturers announcing the presence of *Salmonella* have not used such language.[7] This Court should not issue an injunction against FDA on the basis of Darwin's unsupported allegation.

[6] Darwin's is also mistaken in suggesting that FDA's issuance of a public statement would give rise or contribute to a cause of action. Congress charged FDA with protecting the public health and assuring the safety of foods, *see* 21 U.S.C. § 393, and the Supreme Court has made clear that the government must be free to state an opinion in order for government to function properly. *Shurtleff v. City of Bos., Massachusetts*, 142 S. Ct. 1583, 1589 (2022); *Pleasant Grove City v. Summum*, 555 U.S. 460, 468 (2009).

[7] *See, e.g.*, Stormberg Foods LLC Recalls Chicken Strips and Chicken Crisps Products for Dogs Due to Possible Salmonella Contamination, Jul. 12, 2022, https://go.usa.gov/xSVTc; Woody's Pet Food Deli Recalls Raw Cornish Hen Pet Food for Salmonella Health Risk, Dec. 23, 2021, https://go.usa.gov/xSVTY; The J. M. Smucker Co. Issues Limited, Voluntary Recall of Two Lots of Meow Mix® Original Choice Dry Cat Food for Potential Salmonella Contamination, Apr. 9, 2021, https://go.usa.gov/xSVT4.

II. Darwin's Fails To Show That It Would Face Irreparable Harm

Even if Darwin's were to make the threshold showings of likelihood of success on the merits (it has not), the other factors favor denying injunctive relief. To show that it would suffer irreparable injury absent injunctive relief, Darwin's must show "that irreparable injury is *likely* in the absence of an injunction." *Winter*, 555 U.S. at 22 (emphasis in original). But Darwin's can only speculate.

First, Darwin's fears of irreparable harm are based on speculation about the content of a public statement that FDA has not issued. Its motion alleges that FDA's press release or public statement will label its products "adulterated," Pl. Mot. 1, but as noted, "the content and potential ramifications" of the unissued statement "remain purely hypothetical and speculative," *see Wedgewood*, 2022 WL 1591787, at *5, and FDA would not need to include a finding of adulteration in such a statement.

Second, Darwin's fails to establish that a press release or public statement would likely cause harm to its business. *See* ECF No. 3 at 19. FDA has warned the public about its products twice in the past five years, so Darwin's customers are likely already familiar with its history. ECF No. 4 at 4–6. And by publicly filing a challenge to FDA's unissued press release or public statement and airing FDA's concerns, Darwin's has already disclosed what it seeks to prevent FDA from disclosing. Another FDA statement about its products is unlikely to incur even further reputational or economic harm.

Third, Darwin's has not shown an injury to its First Amendment freedoms. As noted, Darwin's has retained its freedom not to speak. If FDA were to issue a public statement about how *Salmonella* had been detected in some of its products, those freedoms would remain intact.

III. The Balance Of Equities And Public Interest Oppose Injunctive Relief

Finally, the balance of the equities and public interest strongly favor denying injunctive relief: FDA's interest in informing the public about the results of its investigation far outweighs Darwin's interest in avoiding negative publicity. As the *Hoxsey* court explained, "defendants are

performing a public duty when they are urging the use of certain treatments or warning the public against the use of certain treatments." 155 F. Supp. at 378.

Indeed, "any time" the government "is enjoined by a court from effectuating statutes enacted by representatives of its people, it suffers a form of irreparable injury." *Maryland v. King*, 567 U.S. 1301, 1303 (2012) (quoting *New Motor Vehicle Bd. of Cal. v. Orrin W. Fox Co.*, 434 U.S. 1345, 1351 (1977)). That injury is particularly acute where, as here, the decision in question falls within the very core of responsibilities delegated to FDA, and directly implicates the full depth of its scientific and technical expertise. *See*, *e.g.*, *Henley v. FDA*, 77 F.3d 616, 621 (2d Cir. 1996) (deferring to FDA's expertise); *A.L. Pharma, Inc. v. Shalala*, 62 F.3d 1484, 1490–91 (D.C. Cir. 1995); *see also City of Oxford v. FAA*, 428 F.3d 1346, 1352 (11th Cir. 2005) ("the reviewing court may not substitute its judgment for that of the agency"). The deference owed to FDA's expertise in this area weighs strongly against second-guessing any decision FDA might make to inform the public of the results of the *Salmonella* tests.

CONCLUSION

For the foregoing reasons, the Court should deny Darwin's motion for a temporary restraining order or preliminary injunction.

Dated: August 1, 2022

Respectfully submitted,

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